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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,828	11/14/2003	Kamil Paruch	OC01574	2588

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,828

Applicant(s)

PARUCH ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 33-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' election of Group I subject matter with traverse in response filed 10/24/05 acknowledged but is not persuasive. Applicants appear to traverse the restriction based on a "commonality" in the structures and a lack of burdensome search. With regard to the first argument only one ring is fixed, namely the piperidine ring attached to Z. Everything else can vary and it is evident from the range reported for binding activity in the specification that this ring is not solely responsible for activity. Thus the requirements stated in MPEP 803.02 have not been met. With regard to the second part of the traverse, applicants are requested to recheck the fields of search given for compounds of I vs II. There is not even any overlap in classification and thus it is not seen how applicants can conclude that the procedure in the MPEP has not been followed.

Where more than one use exists restriction is in compliance with MPEP 806.05(h). The additional active ingredients present in group V is extensive and unrelated. Additional issues of patentability would be a consideration for these groups, notably sole reliance on screening tests as a reasonable predictor of *in vivo* treatment for all uses claimed and the question of sufficiency of dosage regimens that are commensurate in scope with all pairs of active ingredients embraced for all uses being claimed. Restriction is proper where there is lack of unity of invention and such is not affected by the manner of claiming- i.e. in separate

claims or within a single claim. Note 37 CFR 1.141(a) which states two or more independent, distinct inventions may not be claimed in one application. One application includes the possibility of the separate inventions appearing in one claim or in more than one claim. This is also consistent with PCT Rule 13.3 for PCT cases entering the national stage.

Thus the restriction is deemed proper and is therefore made FINAL.

The objection to the parent history in the Application Data Sheet listing “pending” is withdrawn as PTO staff has informed the examiner that the printer will not include the status for provisional applications.

Claims 33-36 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims recite salt and solvates not included within main claim 1.

Claims 1,3-17 and 31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Reason #2 of the previous action

remains. Applicants' amendments to main claim 1 reciting definitions for "heteroaryl" and "heterocyclyl" that can have as an upper limit 10 atoms does not overcome this rejection. Applicants have not shown a reasonable correlation of enablement commensurate with the claims' scope given the structure-sensitive area of pharmaceuticals in general. As mentioned previously by the examiner, the compounds exemplified are very structurally similar to each other but not to the remaining members claimed. While it is agreed that every member of a Markush group does not require testing, there must be a showing that is representative of the claimed scope. Applicants provide no sound reasoning why one skilled in the art should or would accept the prepared examples (1-16) as being representative (biologically equivalent) of the many hetero rings as R1,R2,R4,R6,R7 still being claimed. Note in *Surrey* previously cited, in which testing done on a group of homogeneous compounds having the same core as herein was deemed not sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein. Note also *In re Fisher* 166 USPQ 18 in which it was emphasized that in unpredictable arts such as the pharmaceutical art, "scope of enablement varies inversely with the degree of unpredictability of the factors involved". Note that claims 33-36 were inadvertently included in this rejection in the previous action.

Claims 33-36 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

Application/Control Number: 10/713,828
Art Unit: 1624

Page 6

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt
Primary Examiner
Art Unit 1624